REMARKS

Claims 51-65 are pending and have been examined on the merits.

In the Final Office Action, the Examiner has maintained the rejection of claims 51-65 under 35 U.S.C. 112, ¶ 1 for allegedly failing to comply with the written description requirement.

Applicant respectfully traverses the rejection.

As previously submitted, the subject matter of claims 51-59 is directed to isolated monoclonal antibodies or fragments thereof, with a light chain variable (V_L) domain comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 43, SEQ ID NO: 44 and SEQ ID NO: 46 and a heavy chain variable (V_H) domain comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 45 and SEQ ID NO: 47. The subject matter of claims 60-65 is directed to pharmaceutical compositions including a carrier and the antibodies or antibody fragments thereof recited in claims 51-59.

The Examiner has taken the position that Applicant's response filed on September 2, 2011 appears to argue that the claimed invention is enabling rather than addressing the Examiner's claim rejection for lack of written description requirement (*e.g.*, bottom of page 2 of the Final Office Action).

Applicant respectfully disagrees with the Examiner's comment.

As set forth above, the presently claimed subject matter is directed to isolated antibodies as defined in claims 51-59 and to their respective pharmaceutical compositions as defined in claims 60-65.

In order to satisfy the written description requirement, the present specification must describe the claimed invention, i.e., an isolated monoclonal antibody or fragment thereof,

comprising a light chain variable (V_L) domain comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 43, SEQ ID NO: 44 and SEQ ID NO: 46 and a heavy chain variable (V_H) domain comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 45 and SEQ ID NO: 47 and the correspondent pharmaceutical compositions, respectively. *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003).

Applicants submit that for the following reasons the present specification satisfies the written description requirement.

First, and as previously submitted, the specification does describe the presently claimed subject matter (*e.g.*, the amino acids corresponding to SEQ ID NO: 43, SEQ ID NO: 44, SEQ ID NO: 45, SEQ ID NO: 46 and SEQ ID NO: 47 are described in Figures 10A, 10B and 10C and from page 22 to page 32; the definition of pharmaceutical composition is found on page 12, lines 13-24 and on page 13, lines 7-11).

Second, the currently pending claims have been amended on May 9, 2011 in response to a Final Office Action issued on May 30, 2010. It is settled law that new or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972).

But this is not the case.

As previously submitted and as repeated above, the currently claimed subject matter is more than adequately supported by the as-filed disclosure.

Third, the Examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art

would not recognize that the written description of the invention provides support for the claims. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976).

In other words, for each claim it must be determined what the claim as a whole covers, by analyzing and giving to each claim its broadest reasonable interpretation in light of and consistent with the written description. *In re Morris*, 127 F.3d 1048, 1053-54, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997).

Applicant respectfully asserts that the Examiner has not met his burden.

On page 3 of the Final Office Action, the Examiner has stated that the claims have failed to indicate which specific antigen the claimed antibody or fragments would interact with, because, based on the definition of an antibody, an antibody is defined by its specificity of reacting to and antigen, not by amino acid fragments. Therefore, without adequate description of the specificity, one of ordinary skill in the art cannot envision what is the claimed antibody or fragment thereof.

However, what the Examiner describes is not the presently claimed subject matter.

As discussed many time before, the presently claimed invention is directed to antibodies of a particular structure, characterized by amino acid sequences which define the light and heavy chain variable domains. The specificity of the antibodies is not part of the presently claimed subject matter and therefore the comment of the Examiner in this regard is completely irrelevant.

Moreover, Applicant respectfully asserts that the Examiner's comment with regard to claims 60-65 is also incorrect.

On page 3 of the Final Office Action (*e.g.*, point 6), the Examiner has stated that the description requirement of the patent statue requires a description of an invention not an indication of a result that one might achieve if one made that invention. Thus, in the present

case, the claims lack adequate description of a "pharmaceutical composition" because the specification has not shown that the claimed antibody or fragment can be used for treating any specific diseases or viral infection, providing clinical benefit. But again, this is not what is presently claimed and this standard to meet the requirement of the written description is incorrect.

The written description requirement is met when each claimed limitation is expressly, or implicitly, or inherently supported in the originally filed disclosure. *In re Robins*, 429 F.2d 452, 456-57, 166 USPQ 552, 555 (CCPA 1970).

Because the specification expressly provides ample support for each claimed limitations, and because the specificity of the antibodies claimed and the type of diseases to be treated with the claimed pharmaceutical compositions are not part of the claimed subject matter, Applicant respectfully requests that this 35 U.S.C. § 112, ¶ 1 rejection be reconsidered and withdrawn.

This response is being filed within the two month shortened statutory period for response, thus, no additional fees are believed to be due. If, on the other hand, it is determined that further fees are necessary or any overpayment has been made, the Commissioner is hereby authorized to debit or credit such sum to Deposit Account No. 02-2275.

An early and favorable action on the merits is earnestly solicited

Respectfully submitted

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